

CORRECTED VERSION

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
22 January 2004 (22.01.2004)

PCT

(10) International Publication Number
WO 2004/006958 A1

- (51) International Patent Classification⁷: **A61K 47/02**, 47/10, 38/18
- (21) International Application Number: **PCT/SI2003/000023**
- (22) International Filing Date: 14 July 2003 (14.07.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: P-200200178 17 July 2002 (17.07.2002) SI
- (71) Applicant (for all designated States except US): **LEK PHARMACEUTICALS D.D.** [SI/SI]; Verovskova 57, 1526 Ljubljana (SI).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **VUKMIROVIC, Andreja** [SI/SI]; Dergomaska 16, 1000 Ljubljana (SI). **ROZMAN, Tanja** [SI/SI]; Ul. Frankolovskih zrtev 11A, 3000 Celje (SI). **SVETEK, Jelka** [SI/SI]; Prusnikova 13, 1210 Ljubljana (SI). **PARIS, Alenka** [SI/SI]; Trzaska 121, 1000 Ljubljana (SI).
- (74) Agent: **KOSAK, Alenka**; Intellectual Property Department, Lek Pharmaceuticals d.d., Verovskova 57, 1526 Ljubljana (SI).
- (81) Designated States (national): AT, AU, BA, BG, BR, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, HR, HU, ID, IL, IN, JP, KR, LT, LU, LV, MK, MX, NO, NZ, PL, PT, RO, RU, SE, SG, SK, TR, UA, US, ZA.
- (84) Designated States (regional): European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).
- Declaration under Rule 4.17:**
— of inventorship (Rule 4.17(iv)) for US only
- Published:**
— with international search report
- (48) Date of publication of this corrected version: 13 January 2005
- (15) Information about Correction:
see PCT Gazette No. 02/2005 of 13 January 2005, Section II
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STABLE PHARMACEUTICAL COMPOSITION COMPRISING ERYTHROPOIETIN

(57) Abstract: The present invention provides a new stable pharmaceutical composition of erythropoietin (EPO) that is stabilized with a combination of a poloxamer polyol and a polyhydric alcohol.

WO 2004/006958 A1

INTERNATIONAL SEARCH REPORT

Receivato

PCT/SI 03/00023 14 JAN 2005

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K47/02 A61K47/10 A61K38/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 178 576 A (CHUGAI SEIYAKU KK,JP) 23 April 1986 (1986-04-23) claims 3,4 example 4	1,3-5,7, 10-13, 19-22
A	US 5 968 899 A (T.SEKINE ET AL.) 19 October 1999 (1999-10-19) claims examples	1-22
A	US 5 656 289 A (Y.W.CHO ET AL.) 12 August 1997 (1997-08-12) claims	1-22
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- * & * document member of the same patent family

Date of the actual completion of the international search

2 December 2003

Date of mailing of the international search report

11/12/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Scarponi, U

INTERNATIONAL SEARCH REPORT

International Publication No

PCT/SI 03/00023

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 00 07627 A (JOHNSON & JOHNSON) 17 February 2000 (2000-02-17) claims examples</p> <p>-----</p>	1-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Publication No

PCT/SI 03/00023

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 178576	A	23-04-1986	JP 61091131 A AT 47037 T CA 1258628 A1 DE 3573533 D1 EP 0178576 A1 US 4879272 A	09-05-1986 15-10-1989 22-08-1989 16-11-1989 23-04-1986 07-11-1989
US 5968899	A	19-10-1999	EP 0803255 A1 WO 9533474 A1	29-10-1997 14-12-1995
US 5656289	A	12-08-1997	AT 98480 T AU 625498 B2 AU 4243289 A AU 4341789 A BG 60849 B1 CA 1339814 C CZ 8905548 A3 DE 68911473 D1 DE 68911473 T2 DK 481989 A EP 0366277 A2 ES 2060785 T3 FI 894637 A ,B, WO 9003164 A2 HK 85596 A HU 54033 A2 HU 9500585 A3 IE 63543 B1 JP 2218609 A JP 2927835 B2 KR 139641 B1 MX 17752 A NO 893896 A NZ 230838 A PL 163635 B1 PT 91850 A ,B RO 108219 B1 RU 2122403 C1 ZA 8907437 A	15-01-1994 16-07-1992 05-04-1990 18-04-1990 31-05-1996 14-04-1998 13-01-1999 27-01-1994 05-05-1994 30-03-1990 02-05-1990 01-12-1994 30-03-1990 05-04-1990 24-05-1996 28-01-1991 30-10-1995 17-05-1995 31-08-1990 28-07-1999 01-06-1998 01-12-1993 30-03-1990 26-03-1991 29-04-1994 30-03-1990 31-03-1994 27-11-1998 26-06-1991
WO 0007627	A	17-02-2000	US 6284234 B1 AU 5669599 A CA 2339231 A1 CN 1303263 T EP 1104280 A2 JP 2003521452 T WO 0007627 A2 US 2002048558 A1	04-09-2001 28-02-2000 17-02-2000 11-07-2001 06-06-2001 15-07-2003 17-02-2000 25-04-2002